UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,750	06/04/2001	Andrew Richard Gorringe	1581.0780000	1196

7590 03/17/2005

Sterne Kessler Goldstein & Fox
1100 New York Avenue NW Suite 600
Washington, DC 20005-3934

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,750	GORRINGE ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-20 and 28-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-20 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and response filed July 19, 2004 is acknowledged. Claims 1-9, 21-27 and 35 have been cancelled. Claim 10, 15-16, 18, 28 and 30-31 have been amended.

2. Upon further review and reconsideration, the finality of the rejection of the Final Office Action, is withdrawn.

New Grounds of Rejection

Claim Objection

3. Applicant is advised that should claim 18 be found allowable, claim 31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 10-14 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter. Claims 10-14 are drawn to a pharmaceutical composition comprising an antibody to a bacterial Cu,Zn-SOD of the dimeric type. Claims 10-14 read on a product that exists in nature. This rejection may be obviated, if the claims are amended to "... a "isolated or purified antibody...".

5. Claims 15-17 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter. Claims 15-17 are drawn to a multivalent vaccine comprising a plurality of Cu,Zn-SODs of the dimeric type wherein said plurality of Cu,Zn-SODs are from the same or different species of gram-negative bacteria. Claims 15-17 read on a product that exists in nature. This rejection may be obviated, if the claims are amended to "... a plurality of "isolated or purified Cu,Zn-SODs of the dimeric type...".

6. Claims 18-20 and 31-33 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter. Claims 18-20 and 31-33 are drawn to a method of treating an individual with a bacterial infection comprising administering a composition comprising a bacterial Cu,Zn-superoxide dismutase of a dimeric type. Claims 18-20 and 31-33 read on a product that exists in nature. This rejection may be obviated, if the claims are amended to "... a isolated or purified Cu,Zn-SODs of the dimeric type...".

7. Claims 28-29 and 34 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter. Claims 28-29 and 34 are drawn to a method of treating an individual with a bacterial infection comprising administering a composition an effective amount of antibody specific to bacterial Cu,Zn-SOD of the dimeric type. Claims 28-29 and 34 read on a product that exists in nature. This rejection may be obviated, if the claims are amended to " ... a isolated or purified Cu,Zn-SODs of the dimeric type...".

8. Claim 30 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter. Claim 30 is drawn to a method of treating an individual with a bacterial infection comprising administering a composition a nucleic acid encoding a bacterial Cu,Zn-SOD of the dimeric type. Claim 30 reads on a product that exists in nature. This rejection may be obviated, if the claims are amended to "... an isolated nucleic acid encoding a Cu,Zn-SODs of the dimeric type...".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 10-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharamaceutical composition comprising an antibody that recognizes *A. pleuropneumoniae* Cu,Zn-SOD, *H. parainfluenzae* Cu,Zn-SOD, *H. ducreyi* Cu,Zn-SOD, *N. meningitidis* Cu,Zn-SOD and *A. actininomycetermcomitans* Cu,Zn-SOD that is protective against lethal infection with *N. meningitidis* does not reasonably provide enablement for a pharmaceutical composition comprising a monoclonal antibody that is protective against *Actinobacillus pleuropneumoniae* or infections caused by gram-negative microorganisms of the genera *Pasteurellaceae, Haemphilius, Salmonella* or *Escherichia* infection nor does the instant

specification provide enablement for a multivalent vaccine that comprising a plurality of bacterial Cu,Zn-SODs of the dimeric type wherein the vaccine provides protective immunity to infection caused by gram-negative bacteria nor does the instant specification provide enablement for a multivalent vaccine comprising a bacterial bacterial Cu,Zn-SODs of the dimeric type and second protein that is not a Cu,ZN-SOD wherein the vaccine provides protective immunity to infection cause by gram-negative bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant specification teaches a monoclonal antibody that recognizes an antibody that recognizes *A. pleuropneumoniae* Cu,Zn-SOD, *H. parainfluenzae* Cu,Zn-SOD, *H. ducreyi* Cu,Zn-SOD, *N. meningitidis* Cu,Zn-SOD and *A. actininomycetermcomitans* Cu,Zn-SOD. This monoclonal antibody is protective against lethal infection with *N. meningitidis*. There is no correlation in the instant disclosure between the claimed pharmaceutical compositions and infections caused by gram-negative bacteria from the genera *Pasteurellaceae, Haemophilus, Salmonella* or *Escherichia*. There is no correlation in the instant disclosure between the claimed multivalent vaccines and infections caused by any gram-negative bacteria.

The state of the art regarding bacterial Cu, Zn SODs is provided below. Knoll et al (*Microbiology, 1995, 141, 227-2279*) teach that Cu,Zn-SODs have been found in bacteria such as *A. pleuropneumoniae*, *H. parainfluenzae*, *H. ducreyi* , *N. meningitidis*, *Pasteurella mulocida* and *A. actininomycetermcomitans* (see the Abstract). Langford et al *(Infection and Immunity, Dec. 1996, p. 5035-5041)* teach that copper- and zinc- super

dismutases (Cu,Zn-SODs) were considered very unusual in bacteria until recently (see the Abstract). Langford et al teach that *A. pleuropneumoniae* Cu,Zn-SOD differs from the Cu, Zn-SODs of the *Haemophilius-Acintobacillus-Pasteurella* group (page 5039). Langford et al teach that it is difficult to imagine that an antibody directed against a periplasmic protein has a significant role in preventing disease and suggests that any protective immune response involving Cu, Zn-SOD may be related to cell mediated immunity (page 5040).

The cited prior art does not make any correlation between Cu, Zn-SODs and there ability to prevent or treat any and all infections caused by a plurality of gram-negative microorganism since the prior art discloses the difficult to imagine that a antibody against a periplasmic protein can be involved in preventing disease. Clearly a great amount of experimentation would be necessary in order to treat or prevent multiple gram-negative infections using a monoclonal antibody bacterial Cu,Zn-SOD of the dimeric type. The specification has not provided enablement for a multivalent vaccine that comprise a bacterial Cu, Zn-SOD of the dimeric type wherein said plurality of Cu,Zn-SODs are the same or different species of gram-negative bacteria used to provide protective immunity against gram-negative species selected from the group consisting of *Pasteurellaceae, Neisseria, Haemphilius, Salmonella* and *Escherichia* nor does the specification provide enablement for a multivalent vaccine comprising a bacterial bacterial Cu,Zn-SODs of the dimeric type and second protein that is not a Cu,ZN-SOD wherein the vaccine provides protective immunity to infection cause by gram-negative bacteria. One skilled in the art would require guidance in order to make

and use the claimed multivalent vaccines in regard to treating or preventing a plurality of gram-negative infections. One skilled in the art would also require guidance in order to make and use the claimed pharmaceutical composition to treating or preventing a plurality of gram-negative infections.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification using the claimed multivalent vaccine to treat or prevent any or all gram-negative infections , 3) there are no working examples presented in the specification that teach the use of the claimed multivalent vaccines, 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level), and 5) the state of the art in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art.

In view of all of the above, it is determined that it would require undue experimentation to make and use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by Langford *(Infection and Immunity, Dec. 1996, p. 5035-5041).*

Claims 10, 11, 13 and 14 are directed to a pharmaceutical composition comprising an antibody to a bacterial Cu,Zn_SOD of the dimeric type and a pharmaceutically acceptable carrier.

Langford et al teach a pharmaceutical composition comprising antibodies to *Actinobacillus pleuropnemoniae*, sodium chloride and Tween 20 (page 5036). Claims limitations such as "wherein said antibody provides protective immunity to *Actinobacillus pleuropneumoniae* infection" and "wherein said antibody displays bactericidal activity" are being viewed as a limitation of intended use. Langford et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re

Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. Claims 18-19, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as anticipated by Wilkes et al *(Infection and Immunity, Jan. 1998, p. 213-217).*

Claims 18-19, 31, 33 and 34 are directed to a method of treating an individual with a bacterial infection comprising administering a composition comprising a bacterial Cu,Zn-superoxide dismutase of the dimeric type.

Wilkes et al teach a method a method of treating mice comprising administering a composition comprising a bacterial Cu, Zn-SOD (SodC mutant) (page 216). Wilkes et al teach that 14 out of 25 mice inoculated with the Sod mutant survived. Wilkes et al teach that the sodC mutant protects mice against exogenous superoxide challenge (216). Wilkes et al teach that sodC mutant was significantly less virulent and Cu, Zn SOD contributes to the virulence of *Neisseria meningitidis* most likely by reducing the effectiveness of toxic oxygen host defenses (see the Abstract).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e.,that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

12. No claims are allowed.

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
February 25, 2005

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600